

Package leaflet: information for the user

Valaciclovir Bluefish 500 mg film-coated Tablets

valaciclovir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Valaciclovir Bluefish is and what it is used for
2. What you need to know before you take Valaciclovir Bluefish
3. How to take Valaciclovir Bluefish
4. Possible side effects
5. How to store Valaciclovir Bluefish
6. Contents of the pack and other information

1. What Valaciclovir Bluefish is and what it is used for

Valaciclovir Bluefish belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

Valaciclovir Bluefish can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)
- treat and prevent HSV infections of the eye

2. What you need to know before you take Valaciclovir Bluefish

Don't take Valaciclovir Bluefish

- If you are allergic (hypersensitive) to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in Section 6).
- If you have ever developed an extended rash associated with fever, enlarged lymph node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.
- Don't take Valaciclovir Bluefish if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir Bluefish.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valaciclovir Bluefish if:

- you have kidney problems

- you have liver problems
- you are over 65 years of age
- your immune system is weak

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Valaciclovir Bluefish.

Take special care with Valaciclovir Bluefish:

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking valaciclovir and contact your doctor or seek medical attention immediately.

Prevent passing genital herpes on to others

If you are taking Valaciclovir Bluefish to treat or prevent genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Other medicines and Valaciclovir Bluefish

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking Valaciclovir Bluefish for treatment of shingles or after having an organ transplant.

Pregnancy, breast-feeding and fertility

Valaciclovir Bluefish is not usually recommended for use during pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir Bluefish while you're pregnant or breastfeeding.

Driving and using machines

Valaciclovir Bluefish can cause side effects that affect your ability to drive.

→ Don't drive or use machines unless you are sure you're not affected.

3. How to take Valaciclovir Bluefish

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment of shingles

- The usual dose is 1000 mg (one 1000 mg tablet or two 500 mg tablets) three times a day.
- You should take Valaciclovir Bluefish for seven days.

Treatment of cold sores

- The usual dose is 2000 mg (two 1000 mg tablets or four 500 mg tablets) twice a day.

- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose
- You should take Valaciclovir Bluefish for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The usual dose is 500 mg (one 500 mg tablet or two 250 mg tablets) twice a day.
- For the first infection you should take Valaciclovir Bluefish for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them

- The usual dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250 mg tablet twice a day.
- You should take Valaciclovir Bluefish until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)

- The usual dose is 2000 mg (two 1000 mg tablets or four 500 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Valaciclovir Bluefish as soon as possible after your surgery.
- You should take Valaciclovir Bluefish for around 90 days after your surgery, until your doctor tells you to stop.

Your doctor may adjust the dose of Valaciclovir Bluefish if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems.

→ Talk to your doctor before taking Valaciclovir Bluefish if any of the above apply.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valaciclovir Bluefish at the same time each day.
- Take Valaciclovir Bluefish according to instructions from your doctor or pharmacist.

People over 65 years of age or with kidney problems

It is very important while you are taking Valaciclovir Bluefish that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you take more Valaciclovir Bluefish than you should

Valaciclovir Bluefish is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy. Talk to your doctor or pharmacist if you take too much Valaciclovir Bluefish. Take the medicine pack with you.

If you forget to take Valaciclovir Bluefish

- If you forget to take Valaciclovir Bluefish, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

The following side effects may happen with this medicine:

Conditions you need to look out for

- severe allergic reactions (*anaphylaxis*). These are rare in people taking Valaciclovir Bluefish. Rapid development of symptoms including:
 - flushing, itchy skin rash
 - swelling of the lips, face, neck and throat, causing difficulty in breathing (*angiodema*)
 - fall in blood pressure leading to collapse.

→ If you have an allergic reaction, stop taking Valaciclovir Bluefish and see a doctor straight away.

Very Common (may affect more than 1 in 10 people):

- headache

Common (may affect up to 1 in 10 people)

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (*photosensitivity*).
- rash

Uncommon (may affect up to 1 in 100 people)

- feeling confused
- seeing or hearing things that aren't there (*hallucinations*)
- feeling very drowsy
- tremors
- feeling agitated

Frequency Not known :

Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir Bluefish a day. They usually get better when Valaciclovir Bluefish is stopped or the dose reduced.

Other uncommon side effects:

- shortness of breath (*dyspnoea*)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (*urticaria*)
- low back pain (kidney pain)
- blood in urine

Uncommon side effects that may show up in blood tests:

- reduction in the number of white blood cells (*leucopenia*)
- reduction in the number of *blood platelets* which are cells that help blood to clot (*thrombocytopenia*)
- increase in substances produced by the liver.

Rare (may affect up to 1 in 1,000 people)

- unsteadiness when walking and lack of coordination (*ataxia*)
- slow, slurred speech (*dysarthria*)
- fits (convulsions)
- altered brain function (*encephalopathy*)
- unconsciousness (*coma*)
- confused or disturbed thoughts
- delirium

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir Bluefish a day. They usually get better when Valaciclovir Bluefish is stopped or the dose reduced.

Other rare side effects:

- kidney problems where you pass little or no urine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax:

+353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Valaciclovir Bluefish

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date (Exp.) refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Valaciclovir Bluefish contains

- The active substance is valaciclovir. Each tablet contains 500 mg valaciclovir (as valaciclovir hydrochloride monohydrate).
- The other ingredients are magnesium stearate, povidone, crospovidone, microcrystalline cellulose, titanium dioxide, hypromellose, macrogol 400 and polysorbate 80.

What Valaciclovir Bluefish look like and contents of the pack

- Valaciclovir 500 mg Tablets are white, capsule-shaped, biconvex, film-coated tablets. The tablets are embossed 'V' on one side and '500' on the other side.
- Your medicine is available in blisters containing 4, 6, 10, 24, 30, 42, 80, 84, 90, 112 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Bluefish Pharmaceuticals AB
P.O. Box 49013,
100 28, Stockholm,
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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Valaciclovir Bluefish 500 mg 500 mg Filmtabletten
Denmark	Valaciclovir Bluefish
Finland	Valaciclovir Bluefish 500 mg tabletti, kalvopäällysteinen/Valaciclovir Bluefish 500 mg filmdragerade tablett
France	Valaciclovir Bluefish 500 mg comprimé pelliculé
Germany	Valaciclovir Bluefish 500 mg Filmtabletten
Ireland	Valaciclovir Bluefish 500 mg 500 mg film-coated Tablets
Portugal	Valaciclovir Bluefish 500 mg, comprimidos revestidos por película
Sweden	Valaciclovir Bluefish 500 mg filmdragerade tablett
Island	Valaciclovir Bluefish 500 mg filmhúðaðar töflur

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